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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,470	11/25/2003	Hilde De Reuse	02356.0080-01	6378
22852	7590	04/27/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/720,470

**Applicant(s)**

DE REUSE ET AL.

**Examiner**

Ginny Portner

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 6-12 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6-12, 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/23/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 6-12 and 25-28 are pending.

#### ***Priority***

1. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

- a. The first sentence of the specification states that Application serial number 09/742,361 was filed December 22, 2003; this is not the case. Application serial number 09/742,361 was filed on December 22, 2000.
- b. US Application 09/107,383 was not filed on June 30, 1988, but on June 30, 1998.
- c. The issue date for US Pat. No 5,190,667 has not been set forth in the first sentence of the Specification.
- d. PCT/EP99/04490 does not claim priority to 09/107,383 and therefore is not a continuation in part of 09/107,383 as asserted by the amended first sentence of the Specification.

#### ***Information Disclosure Statement***

2. The information disclosure statement filed November 23, 2003 has been considered.

*Drawings*

3. The drawings are objected to because The drawings refer to frames 3A and 3B and the Brief Description of the Drawings does not refer to each of the frames shown in the figures. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 6-7, 9-11, 25-27 rejected under 35 U.S.C. 102(e) as being anticipated by Labigne et al (US Pat. 6,258,359 ).

Labigne et al disclose a method of treating H.pylori infection through formulating UreI polypeptide into a composition to induce “antibodies which interfere with the activation process of the urease apoenzyme (see col. 10, lines 21-28)”, wherein the antibodies are induced in vivo in man or animal (see col. 9, 31-35) the method comprising the step of: administering the composition (see col. 9, line 33).

Labigne et al also disclose a method of passive immunization (see col. 9, lines 38-39), of a human or animal to treat H.pylori infection (see col. 10, lines 24-28), with anti-UreI (see col.

Art Unit: 1645

10, lines 6-8 and col. 110, claims 19-20) antibodies (polyclonal or monoclonal antibodies) the method comprising the step of : administering anti-UreI antibodies to the animal by any suitable route, wherein the antibodies "interfere with the activation process of the urease apoenzyme (see col. 11, lines 27-32)". The reference anticipates the instantly claimed invention.

6. Claims 6-7,12, 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Iverson et al (US Pat. 6,124,271).

Iverson et al disclose a method of treating H.pylori infection (see all claims, col. 20-22)., the method comprising the step of:

administering H.pylori antisense oligomer (see claim 1) which will inhibit H.pylori urease (see claim 3), the composition being administered together with a pharmaceutically acceptable carrier, specifically a transport moiety that may be galactose, arabinose, a polypeptide or a polymer matrix (alginate, sucralfate, cellulose, a natural gum (see claims 14 and 15)). The reference anticipates the instantly claimed invention.

7. Claims 6-11,25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakazawa et al (US Pat. 5,214,053) .

8. Nakazawa et al disclose a method of treating H.pylori infection(see claims 16-20)., the method comprising the step of:

administering a thiourea derivative and antimicrobial agent and an antiulcer agent (see title) , the composition being administered together with a pharmaceutically acceptable carrier (see claims 1-12). The reference anticipates the instantly claimed invention, as Nakazawa et al

Art Unit: 1645

discloses the thiourea compositions have antimicrobial activity against *Helicobacter pylori* through inhibiting cell viability/growth (see all claims and examples).

9. Claims 6-11,27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartmann (US Pat.5,900,410) as evidenced by Nawaz et al (1994).

Hartmann (US Pat. 5,514,660) disclose a method of treating *H.pylori* infection (see claims 1-15), the method comprising the step of:

administering a divalent cation of Mg (magnesium), an antibiotic, and urea together with (see claims 10-11) with a pharmaceutically acceptable carrier (see col. 1, lines 61-62 "liquid mixture or gel").

The reference inherently anticipates the instantly claimed invention, as Nawaz et al provide evidence that aliphatic amidases (*Hpylori* UreI is an aliphatic amidase) are inhibited by divalent cations (see Nawaz abstract, teaches Mg divalent cation having inhibitory activity for an aliphatic amidase).

10. Claims 6-7 are rejected under 35 U.S.C. 102(a) as being anticipated by WO97/26908. WO97/26908 disclose a method of treating *Helicobacter pylori* infection, the method comprising the step of :

Administering (see page 11, paragraphs 1-4 and Table 3) in vivo (see page 5, last paragraph) a composition comprising thiocyanate, a peroxide donor and lactoperoxidase, together with a pharmaceutically acceptable carrier (see page 10, paragraphs 2-4), wherein

Art Unit: 1645

thiocyanate would serve to inhibit H.pylori's aliphatic amidase UreI as Gregoriou et al provides evidence that cyanate is an inhibitor of amidase activity (see Gregoriou et al abstract).

Inherently WO97/26908 anticipates the instantly claimed invention.

11. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Zopf (US Pat. 5,514,660) as evidenced by Gregoriou et al (1979).

Zopf (US Pat. 5,514,660) disclose a method of treating H.pylori infection(see claims 1-18), the method comprising the step of:

administering a cyanate derivative together with other antiulcerative compounds (see claims 10-11) , the composition being administered together with a pharmaceutically acceptable carrier (see claims 10-11).

The reference inherently anticipates the instantly claimed invention, as Gregoriou et al (1979) provide evidence that aliphatic amidases (Hpylori UreI is an aliphatic amidase) are inhibited by cyanate.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Labigne et al (US Pat. 5,986,051) is cited to show compositions of UreI antibodies (see claims)

14. Claesson et al (US Pat. 6,149,908) is cited to show a method of treating H.pylori infection.

15. Hasegawa et al (US Pat. 5,190,961) is cited to show methods of treating H.pylori infection with a thiourea derivative.

16. Polak et al (US Pat. 5,409,903) is cited to show methods of treating H.pylori infection with divalent cations (see all claims)

17. Rektorschek et al (April 2000) is cited to show irreversible inhibition of urease by a protonophore.

Art Unit: 1645

18. Rosenstein (1986) is cited to show urease inhibitors to include urea, acetohydroxamic acid, caprylohydroxamic acid, methoxybenzohydroxamic acid, and glycinohydroxamic acid (see pages 255-256).

19. Skouloubris et al (1997) is cited to show characterization of H.pylori amidase.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
April 20, 2004

  
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